EXHIBIT I

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE:	)	
NEURONTIN MARKETING, SALES PRACTICES	)	CA No. 04-10981-PBS
AND PRODUCTS LIABILITY LITIGATION	)	Pages 107 - 360

DAUBERT HEARING - DAY TWO

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE
and
JUSTICE MARCY S. FRIEDMAN
NEW YORK SUPREME COURT

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
June 20, 2008, 9:10 a.m.

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A. Well, they were asking to be educated.
Q. Well, I will direct the questions, and you may answer my questions "yes" or "no," okay? If you have to explain, if you really need to explain, the Court will interrupt me.
Now, I want to ask you about Mr. Altman's participation. You understand that Mr. Altman has been in active participation in this litigation in behalf of plaintiffs, correct?
A. Yes.
Q. And knowing that, wouldn't you agree that Mr. Altman and his employees have a financial interest in the outcome of this litigation?
JUDGE SARIS: You know, this isn't a jury.
MR. BARNES: Well, no, I understand, but, your Honor, it goes to her autonomy as an expert witness and having a law firm prepare a general causation report wholesale. May I make a proffer?
MR. FINKELSTEIN: This is ridiculous, Judge. It's absolutely --
JUDGE SARIS: I mean, if you want to use your hour this way. I'd much prefer to get to the science. We keep harping on that.
So let me just understand this chart. A PRR is a proportional reporting ratio? What does that mean?
THE WITNESS: If I want to compare two drugs and

see if one drug is different than another one in causing a bad effect, one way I can do it is to say, okay, for Drug A I'm going to divide its bad effects by the total number of effects that that drug has; and then I'm going to compare drug B, how many bad effects does it cause divided by its total number of adverse events? So if one causes 10 headaches out of 100, it would be 10 over 100. If the other one causes 7 headaches and they have 100, it would be 10 over 100 versus 7 over 100. And by doing that, you can say, in a common family of drugs, is there a difference in the percentage of headaches reported with one drug compared to the other? It's a simple way of comparing across families. And if you divide the one ratio by the other ratio, it's called a PR ratio.
JUDGE SARIS: And all these numbers on the bottom on the X axis, what do those denote?
THE WITNESS: Those represent different points in time of adverse events collected. So one of the things that I tried to do --
JUDGE SARIS: Oh, so it says 1998, 19 -- so those are dates?
THE WITNESS: Yes. They're reporting periods for these data, yes.
JUDGE SARIS: And I guess what you're being criticized for is that you yourself didn't go through to make

sure, to use your analogy, that there was a headache? Mr. Altman did that?
MR. BARNES: I'm sorry, your Honor, I didn't hear your question.
JUDGE SARIS: You yourself didn't go through each adverse report and determine whether there was a headache, to use your metaphor?
THE WITNESS: Mr. Altman filtered the FDA database to generate these data. And the reason I used him is, he does the same work for me when I'm submitting applications to the FDA. FDA has reviewed his work in this manner, has approved new drugs based on his work. So because FDA has found his material acceptable, I also use it for this work.
JUDGE SARIS: So how much of it is subjective in this kind of analysis? In other words, if someone says they have a headache, is that used as a proxy for depression?
THE WITNESS: No, it's not subjective because we use the terms exactly as they appear in the FDA's database.
JUDGE SARIS: So the FDA database will say "depression" or "suicide"? What did you use to generate these numbers? What adverse -- what did you call them, substitute end points?
THE WITNESS: I did not use those in this database, your Honor. If you look at the top of the table, these represent the high-level terms in the database of suicidal

and self-injurious behavior.
JUDGE SARIS: And suicidal is suicidal attempts, completions?
THE WITNESS: Yes.
JUDGE SARIS: And suicidal ideation?
THE WITNESS: Yes.
JUDGE SARIS: And self-injurious means, would that be like cutting?
THE WITNESS: Yes. FDA defines a series of self-injurious behaviors. It would include that as well, yes.
JUDGE SARIS: So you've taken whatever the FDA has said?
THE WITNESS: How FDA has coded the database.
JUDGE SARIS: So assuming for a minute --
MR. BARNES: A couple of points. I'll just proffer what my concern is. Dr. Blume is using a method, as she has described it up here, where Mr. Altman has been -- this method, this approach has been specifically excluded in a prior case as being unreliable on issues of --
JUDGE SARIS: No offense to him. Isn't it like asking my secretary, "Take everything from the reports that says suicide or self-injury, and, like, type it in"? I mean, no offense to him, but, I mean, isn't that what we're talking about?

MR. BARNES: Not at all. Not at all. Not at all. And let me tell you -- let me just --

MR. FINKELSTEIN: We submitted this, your Honor.

JUDGE SARIS: Well, let me ask you. Is that your understanding of what it is?

THE WITNESS: The FDA adverse event database is a huge database that requires filtering across its various hierarchy terms. My understanding is that Mr. Altman has developed a method, has a method to filter those, and that's what he does. There is no subjective interpretation. We use the terms as FDA defines them.

MR. BARNES: Your Honor, I'll make a proffer here. Even under the method -- and I'll show you in the pharmacovigilance document -- all this -- assume this is in fact what they are purporting it to be. All it is is evidence of a signal. It is explicitly prohibited to be considered on issues of causation by the very document they cite, the pharmacovigilance document in 2005, and I can show it to you.

JUDGE SARIS: Maybe. I just wanted to understand your point about Altman.

MR. BARNES: The point about Mr. Altman is that --

JUDGE SARIS: I got the whole thing now, okay.

MR. BARNES: I will give you a cite on this point that I think is important. It's In Re: Meridia Products

Liability Litigation, 328 F. Supp. 791, and the Court held after a similar hearing, "Even readers with only a casual understanding of statistics can recognize that this evidence does not speak to the issue of causation, and therefore cannot create a genuine issue of causation --"

JUDGE SARIS: Excuse me. That's a legal argument. We'll get to that. I just want factually I understand the dispute, so why don't we just move on.

MR. BARNES: Okay.

JUSTICE FRIEDMAN: I would like to ask Dr. Blume a question. Are you currently involved in obtaining approvals for pharmaceutical products from the FDA?

THE WITNESS: Absolutely. Our last approval was in February of this year.

JUSTICE FRIEDMAN: And this was not for -- it had nothing to do with any litigation?

THE WITNESS: No. Eighty percent of our practice is devoted to working with pharmaceutical companies with FDA.

JUSTICE FRIEDMAN: And when you submit these approvals, you are working with FDA directives or regulations that tell you what you have to submit, correct?

THE WITNESS: Yes.

JUSTICE FRIEDMAN: But you are not making findings of causation, are you?

THE WITNESS: As I noted earlier, our Code of

Federal Regulations specifically notes that causation isn't required. In fact, causation is not required for product effectiveness, so it's certainly not required for product safety.

JUSTICE FRIEDMAN: No, I understand that, and I recall that testimony, but it is not part of what you do in your regular course of business outside of litigation to make assessments of causation, is it?

THE WITNESS: If we have a study, a randomized clinical trial study, that shows the drug has a significant improvement in whatever we're looking at over placebo, we will say that it appears that this drug is associated with a clinical improvement. If it's statistically significant, you can argue that it caused that improvement, the drug was responsible for that improvement.

JUSTICE FRIEDMAN: But you're not making the determination as to whether the individual studies are statistically significant, are you?

THE WITNESS: Well, we have a biostatistician who does that.

JUSTICE FRIEDMAN: You're calling them to the attention of the FDA, but somebody else is determining their statistical significance? Is that correct? You just said there's a biostatistician?

THE WITNESS: Yes, we have a biostatistician who

runs the statistics. And then our disks, our tapes, statistical tapes, are submitted to FDA along with our applications; and FDA statisticians use our tapes to either confirm, or if they have a question, to ask us a question.

JUSTICE FRIEDMAN: Thank you.

Q. One other point. Approvals in your line of work are based upon randomized controlled clinical trials, correct?

A. Well, if it's possible to do them, yes, they are.

Q. And every one of your new drug applications has been supported by randomized controlled clinical trial to get approval?

A. While I was still at Mylan, we did an orphan drug where it was not permitted to allow patients to have a placebo, so that NDA, of course, could not be based upon a placebo-controlled trial. But other than cancer trials, AIDS types of trials, orphan drugs, most of them are placebo-controlled.

Q. Randomized controlled trials, right?

A. Well, yes, if it's possible to do it, it is the gold standard for effectiveness.

JUDGE SARIS: Do you have any explanation about why Neurontin jumps up so dramatically?

MR. BARNES: Well, that's what I want to talk about, okay?

JUDGE SARIS: If you can just go back one second.